



PATENT
Atty. Docket No. 2852 PRO (203-3408)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Scott Cunningham **EXAMINER:** Gary Jackson
SERIAL NO.: 10/621,759 **ART UNIT:** 3763
FILING DATE: July 17, 2003 **DATED:** April 24, 2006
FOR: **SURGICAL NEEDLE**

Mail Stop Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

BRIEF ON APPEAL

Sir:

This is an appeal from a Final Office Action dated November 23, 2005 in the above-identified application. This Brief is accompanied by the requisite fees set forth in 37 C.F.R. § 41.20(b) (2).

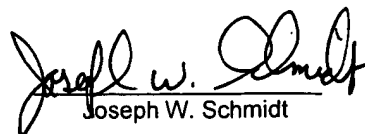
I. REAL PARTY IN INTEREST

The real party in interest for this application is United States Surgical, a Division of Tyco Healthcare Group, LP.

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

I hereby certify that this correspondence is being deposited on date below with the United States Postal Service as first class mail, postpaid in an envelope, addressed to the: Mail Stop Appeal Briefs, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: April 24, 2006


Joseph W. Schmidt

II. RELATED APPEALS AND INTERFERENCES

Appellant, appellant's legal representative and/or the assignee of appellant's interest in the above-identified application are not aware of any related appeals, interferences or judicial proceedings which may be related to, directly affect, or be directly affected by or have a bearing on any decision by the Board of Patent Appeals and Interferences in this appeal.

III. STATUS OF CLAIMS

The instant application was originally filed with 2 claims. New claims 3-12 were presented by amendment. Independent claims 1, 3, and 10 and dependent claims 2, 4-9, and 11-12 are pending in this application and are involved in this Appeal. Each of these claims stand finally rejected as set forth in the Final Office Action dated November 23, 2005 (hereinafter "the Final Office Action") and the Advisory Action dated March 7, 2006. An accurate copy of Claims 1-12 is provided in the Claims Appendix.

IV. STATUS OF AMENDMENTS

A Response to the Final Office Action was filed January 23, 2006. No amendments to the claims were presented in the Response. An Advisory Action mailed March 7, 2006 indicated that the Response was considered but failed to place the application in condition for allowance.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Reference is made to Figure 1 of the drawings of the subject application reproduced hereinbelow for a discussion of the claimed subject matter. The present invention is

directed to a surgical needle 10 (Specification page 4, line 9). The surgical needle 10 has a taper point profile designed to resist bending loads applied to the needle (Specification page 4, lines 15-18). The taper point profile of the needle has a varied taper angle defining a smaller taper ratio in a first region adjacent the tip of the needle relative to a second region proximal of the first region (Specification page 4, lines 19-23; page 5, lines 15-18). This alternating and relative small taper point profile arrangement, in turn, provides an enlarged needle end relative to conventional taper point needles, which is desirably more resistant to breakage during use in a surgical procedure such as an ophthalmic surgery, while providing sufficient penetration performance. Specifically, even in view of its enlarged character or profile, the nature of the alternating tapered regions permits unexpected ease of passage of the needle through tissue.

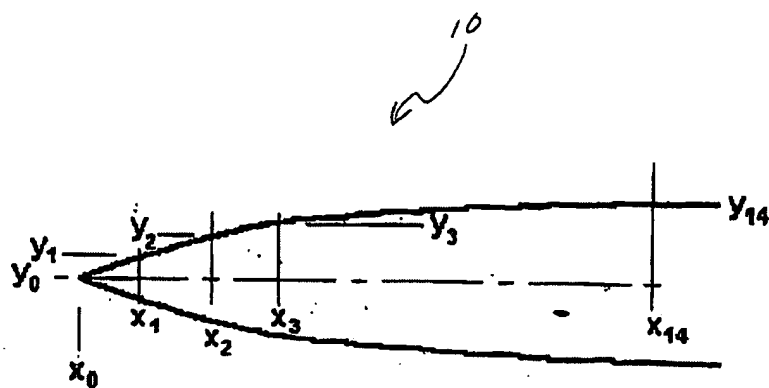


FIG. 1

specific configuration defined by three tapered regions which provide a relatively slender profile to the needle end. Silverman '422 discloses a suture needle with a conical point and a tip portion extending from the conical point and having a plurality of cutting edges; and

2. Whether the surgical needle of claims 1-12 is obvious over Smith '875.

VII. ARGUMENTS

In finally rejecting claims 1-12 under 35 U.S.C. § 103(a), the PTO has completely ignored the fact that neither of the applied references, alone or in combination, teach or suggest the arrangement and values of the critical taper ratios as recited in the surgical needle of independent claims 1, 3, and 10.

The patentability of three separate groups of claims are separately argued herein, namely, (1) including claims 1-2, (2) including claims 3, 4, 5, 8 and 9 and (3) including claims 6, 7, 10, 11 and 12.

A. Smith '875 in view of Silverman '422 Fails to Render Obvious The Recited Surgical Needle

The Examiner has rejected independent claims 1, 3, and 10 and dependent claims 2, 4-9, and 11-12 as being obvious under 35 U.S.C. § 103(a) over Smith '875 in view of Silverman '422. The rejection of these claims should be reversed.

1. Grouping of claims 1-2

Contrary to the positions taken by the PTO, Smith '875 in view of Silverman '422 does not render obvious claims 1-2. Smith '875 discloses a taper point needle having three

The taper ratio of the tapered portion of the needle 10 is defined according to the following equation:

$$\text{Taper Ratio} = (X_{n2} - X_{n1}) / (2Y_{n2})$$

where: X_{n1} = the point along the needle taper segment which is closest to the tip;

X_{n2} = the point along the needle taper segment which is further away from the tip; and

$2Y_{n2}$ = the diameter of the needle which intersects the point X_{n2} .

Independent claim 1 recites a surgical needle having an average taper ratio of a first region defined by X_3 - X_0 of approximately 2.76:1 and an average taper ratio of a second region defined by X_{14} - X_3 of approximately 5.65:1. Independent claim 3 recites a “needle member...defining a non-linear tapered configuration and being devoid of edges...and defining a first region having an average taper ratio less than about 11:1, and a “second region having an average taper ratio less than about 12:1”. Independent claim 10 recites a surgical needle having a needle end portion “being devoid of an edge and defining a first region having an average taper ratio of less than about 3:1 and a second region having an average taper ratio of less than about 6:1”.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The following issues are on appeal:

1. Whether the surgical needle of claims 1-12 is obvious over U.S. Patent No. 5,913,875 to Smith et al. (hereinafter “Smith ‘875”) in view of U.S. Patent No. 5,464,422 to Silverman (hereinafter “Silverman ‘422”). Smith ‘875 discloses a tapered needle having a

tapered regions of significantly large tapers, e.g., 12:1, 6:1 to 11:1 and 12:1. Accordingly, the resulting needle end of Smith '875 is relatively slender or narrow. Silverman '422 is directed to a surgical needle having a shaft portion, a tip portion 13, a conical point portion 15 and a point 17. The tip portion 13 includes a constant or linear taper. It is the PTO's position that "the patents to Smith '875 and Silverman '422 clearly suggests it would have been obvious to one having ordinary skill in the art to modify the Smith '875 and Silverman '422 needle to have ratios as recited in the above claims to obtain the desired strength and penetration characteristics." However, the PTO fails to point to any specific teachings in the references which meet the critical taper ratios defined in the claims. Rather, the PTO relies on the following statement as a "teaching" that the taper ratios of needle can be adjusted to have desired results:

"Those skilled in the art will appreciate that the length of the tapered segment 100, as well as tapered segments 120 and 140, will vary in accordance with the size of the needle wire used, the strength and penetration resistance characteristics desired (i.e., tissue piercing, resistance to bending, ease of penetration and the like) - 3:43-4:22 of Smith '875."

However, this passage is directed to altering the "lengths" of the tapered segments not the values of any taper ratios, particularly, not within the manner recited in the independent claims.

Neither this example nor the passage identified by the PTO provides a suggestion or motivation to modify the Smith '875 needle to have the taper ratio arrangement of independent claim 1.

This arrangement includes taper ratios which are substantially less than, e.g., 2.76:1 and 5.65:1, than those taught or suggested by Smith '875 or Sullivan '422, and, as a result defines a relatively enlarged, e.g., less slender needle end. Accordingly, it is respectfully submitted that

the PTO has failed to meet its case of prima facie obviousness with respect to these features of the pending claims 1 and 2. (“The PTO bears the burden of establishing a case of prima facie obviousness”) In re Bell, 991 F.2d 781 (Fed. Cir. 1993).

Furthermore, assuming arguendo, that the “taper ratios” of Smith ‘875 could be altered to achieve desired results, Smith ‘875 does not teach or suggest an arrangement where the taper ratios become greater or increase from the tip towards the main body portion of the needle, i.e. having a small average taper ratio of, e.g., 2.76:1 adjacent the tip followed by a larger taper ratio of, e.g., 5.65:1, towards the main body of the needle. Rather, with Smith ‘875-the exact opposite arrangement is disclosed, i.e., with Smith ‘875 the largest taper ratio is adjacent the tip followed by a smaller taper ratio (see independent claim 1 of the Smith ‘875 patent). Moreover, Smith ‘875 teaches away from this arrangement in that it would increase resistance to penetration (Smith ‘875, col. 1, lines 35-44). Accordingly, given these disclosures, one skilled in the art reading Smith ‘875 also would not look to modify the needle segments to have taper ratios increasing from the tip towards the body portion of the needle, let alone the specific taper ratios recited in independent claim 1.

2. Grouping of claims 3, 4, 5, 8 and 9

Smith ‘875 in view of Silverman ‘422 does not render obvious claims 3, 4, 5, 8 and 9. Many of the comments presented hereinabove in connection with the discussion of the grouping of claims 1-2 are repeated herein. With further regard to independent claim 3, there is no teaching or suggestion to modify the needle of Smith ‘875 or Silverman ‘422 to achieve the “edgeless” “non-linear tapered configuration” having a “first region” adjacent the needle tip with

an average taper ratio of “less than about 11:1” and a “second region” having an average taper ratio “less than about 12:1.” Again, these specific taper ratios are not taught or suggested by Smith ‘875 or Sullivan ‘422. Moreover, these recited ratios provide an enlarged profile adjacent the needle tip which is directly contrary to the objectives such as reduced resistance to tissue penetration, etc. of the Smith ‘875 and the Silverman ‘422 patents discussed hereinabove. Furthermore, the taper ratios increase toward the main portion of the needle in direct contrast to the disclosure of Smith ‘875. Thus, Smith ‘875 in view of Silverman ‘422 fails to anticipate or render obvious any of claims 3, 4, 5, 8 and 9.

3. Grouping of claims 6, 7, 10, 11 and 12

Smith ‘875 in view of Silverman ‘422 does not render obvious claims 6, 7, 10, 11, and 12. Many of the comments presented hereinabove in connection with the discussion of the grouping of claims 1-2 and the grouping of claims 3, 4, 5, 8 and 9 are repeated herein. With further regard to claims 6, 7, 10, 11 and 12, these claims require a needle end portion being devoid of an edge(s) with a first region having an average taper ratio of less than about 3:1 and a second region an average taper ratio of less than about 6:1. As indicated hereinabove, this arrangement provides for a relatively enlarged profile not contemplated in any way, shape or form by Smith ‘875 or Silverman ‘422. Moreover, these taper ratios are substantially less than those disclosed by Smith ‘875 and increase away from the needle point in direct contrast to Smith ‘875. Furthermore, Silverman ‘422 incorporates a plurality of cutting edges.

B. Smith '875 Fails to Render Obvious the Recited Surgical Needle

The Examiner has rejected independent claims 1, 3, and 10 and dependent claims 2, 4-9, and 11-12 as being obvious under 35 U.S.C. § 103(a) over Smith '875. The rejection of these claims should be reversed.

1. Grouping of Claims 1-2

As discussed hereinabove, the combination of Smith '875 and Silverman '422 fails to teach or suggest the recited arrangement and values for the taper ratios recited in independent claim 1. Accordingly, for at least the reasons stated hereinabove, Smith '875 considered individually can not render claims 1 and 2 obvious. In particular, Smith '875 fails to teach the specific taper ratios defined in the recited claims which provides for a relatively enlarged needle end in direct contrast to the teachings of Smith '875.

2. Grouping of Claims 3, 4, 5, 8 and 9

As discussed hereinabove, the combination of Smith '875 and Silverman '422 fails to teach or suggest the recited arrangement and values for the taper ratios recited in claim 3, 4, 5, 8 and 9. Accordingly, for at least the reasons stated hereinabove, Smith '875 considered individually can not render these claims obvious. In particular, Smith '875 fails to teach the specific taper ratios defined in the recited claims which provides for a relatively enlarged needle end in direct contrast to the teachings of Smith '875.

3. Grouping of Claims 6, 7, 10, 11 and 12

As discussed hereinabove, the combination of Smith '875 and Silverman '422 fails to teach or suggest the recited arrangement and values for the taper ratios recited in claims 6, 7, 10, 11 and 12. Accordingly, for at least the reasons stated hereinabove, Smith '875 considered individually does not render these claims obvious. In particular, Smith '875 fails to teach the specific taper ratios defined in the recited claims which provides for a relatively enlarged needle end in direct contrast to the teachings of Smith '875.

VIII. CONCLUSION

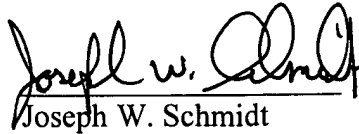
Applicant's invention is directed to a new and novel surgical needle having a specific taper ratio arrangement, which provides unexpected results with respect to needle passage even in view of the decreased relative ratio values. In view of the forgoing analysis and remarks, it is clear that the surgical needle recited in independent Claims 1, 3 and 10 is rendered obvious by Smith '875 and/or Silverman '422 whether considered individually or in any proper combination, in whole or in part. For at least the foregoing reasons and remarks, it is respectfully submitted that:

The surgical needle of Claims 1-12 is not obvious over the taper point needle disclosed in Smith '875 in view of the suture needle of Silverman '422 and therefore the rejection should be reversed; and

Application Serial No. 10/621,759
Brief on Appeal dated April 17, 2006
Reply to Final Office Action mailed January 23, 2006

The surgical needle of Claims 1-12 is not obvious over the taper point needle disclosed in Smith '875 and therefore the rejection should be reversed.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Joseph W. Schmidt", written over a horizontal line.

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VIII. CLAIMS APPENDIX

1. A surgical needle which comprises:
a base portion having a root diameter; and
a tapered end portion extending from said base portion to a pointed end, the tapered end portion defining at least a first and second region, wherein the first region having an average taper ratio of approximately 2.76:1 and the second region having an average taper ratio of approximately 5.65:1.
2. The surgical needle according to claim 1 wherein the first region incorporates a length which is approximately 1/5 of the overall length of the tapered end portion.
3. A surgical needle, which comprises:
an elongated needle member including a base portion having a root diameter and a needle end portion extending to a needle tip, the needle end portion defining a non-linear tapered configuration and being devoid of edges, the needle end portion defining a first region adjacent the needle tip and a second region adjacent the first region, the first region having an average taper ratio less than about 11:1, the second region having an average taper ratio less than about 12:1.
4. The surgical needle according to claim 3 wherein the first region has an average taper ratio less than about 6:1.

5. The surgical needle according to claim 4 wherein the second region has an average taper ratio less than about 8:1.

6. The surgical needle according to claim 5 wherein the first region has an average taper ratio of less than about 3:1.

7. The surgical needle according to claim 6 wherein the second region has an average taper ratio of less than about 6:1.

8. The surgical needle according to claim 3 wherein the first region incorporates a length which is at least about 1/5 of the overall length of the tapered end portion.

9. The surgical needle according to claim 3 wherein the needle end portion defines a general parabolic configuration.

10. A surgical needle, which comprises:
an elongated needle member including a base portion and a needle end portion extending to a needle tip, the needle end portion being devoid of an edge and defining a first region adjacent the needle tip and a second region adjacent the first region, the first region having an average taper ratio of less than about 3:1 and the second region having an average taper ratio of less than about 6:1.

11. The surgical needle according to claim 10 wherein the needle end portion defines a non-linear tapered configuration.

12. The surgical needle according to claim 10 wherein the needle tip is pointed.

Application Serial No. 10/621,759
Brief on Appeal dated April 17, 2006
Reply to Final Office Action mailed January 23, 2006

IX. EVIDENCE APPENDIX

None.

Application Serial No. 10/621,759
Brief on Appeal dated April 17, 2006
Reply to Final Office Action mailed January 23, 2006

X. RELATED PROCEEDINGS APPENDIX

None.